

## PATENT COOPERATION TREATY

by fax and post

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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PCT

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing  
(day/month/year)

07.11.2001

Applicant's or agent's file reference  
661924

## IMPORTANT NOTIFICATION

International application No.  
PCT/JP00/03944International filing date (day/month/year)  
16/06/2000Priority date (day/month/year)  
24/06/1999Applicant  
SAGAMI CHEMICAL RESEARCH CENTER et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the International application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

## 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the International application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/

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Form PCT/IPEA/418 (July 1992)

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

### (PCT Article 36 and Rule 70)

Applicant's or agent's file reference 661924	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP00/03944	International filing date (day/month/year) 16/06/2000	Priority date (day/month/year) 24/06/1999
International Patent Classification (IPC) or national classification and IPC C12N15/12		
Applicant SAGAMI CHEMICAL RESEARCH CENTER et al.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li>I <input checked="" type="checkbox"/> Basis of the report</li> <li>II <input type="checkbox"/> Priority</li> <li>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li>IV <input type="checkbox"/> Lack of unity of invention</li> <li>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li>VI <input type="checkbox"/> Certain documents cited</li> <li>VII <input type="checkbox"/> Certain defects in the international application</li> <li>VIII <input type="checkbox"/> Certain observations on the international application</li> </ul>		

Date of submission of the demand 18/01/2001	Date of completion of this report 07.11.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Young, C Telephone No. +49 89 2399 7877



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International application No. PCT/JP00/03944

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):  
**Description, pages:**

1-75 as originally filed

**Claims, No.:**

1-7 as originally filed

**Drawings, sheets:**

1-8 as originally filed

**Sequence listing part of the description, pages:**

1-41, as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

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- the description,      pages:
- the claims,      Nos.:
- the drawings,      sheets:

5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- the entire international application.
- claims Nos. 1-7 partially.

because:

- the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- no international search report has been established for the said claims Nos. 1-7 (partially).

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- the written form has not been furnished or does not comply with the standard.
- the computer readable form has not been furnished or does not comply with the standard.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)                    Yes: Claims 1-7  
                                  No: Claims

Inventive step (IS)           Yes: Claims  
                                  No: Claims 1-7

Industrial applicability (IA) Yes: Claims  
                                  No: Claims 1-7

**2. Citations and explanations**  
**see separate sheet**

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International application No. PCT/JP00/03944

Reference is made to the following documents:

D1: DATABASE EMBL [Online] EBI; ACC.NO.: AB023224, 9 April 1999 (1999-04-09) NAGASE ET AL.: 'Homo sapiens mRNA for KIAA1007, partial cds.' XP002151125 -& NAGASE ET AL.: 'Prediction of the coding sequences of unidentified human genes. XIII. The complete sequences of 100 new cDNA clones from brain which code for large proteins in vitro' DNA RESEARCH, vol. 6, 26 February 1999 (1999-02-26), pages 63-70

D2: DATABASE EMBL [Online] EBI; ACC. NO.: AA913157, 16 April 1998 (1998-04-16) STRAUSBERG: 'National cancer institute, Cancer genome anatomy project'

D3: WO 98 21328 A (KATO SEISHI ;PROTEGENE INC (JP); SEKINE SHINGO (JP); SAGAMI CHEM R) 22 May 1998 (1998-05-22)

**Re Item V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

The International Search Authority informed the applicant of a lack of unity within the present application. As no further additional search fees were paid the search was restricted to the first invention namely SEQ ID 1,11 and 21. This forms the basis of the present written opinion.

D1 discloses an amino acid sequence which is 99.6% identical to SEQ ID 1 over a 226 amino acid overlap. D2 discloses an EST bearing 99.7% identity to SEQ ID 11 over a 418 base pair overlap. Formally novelty is acknowledged for the claimed sequences. Although, in all probability the discrepancy between the prior art and the claimed sequences may lie in the error prone technique of DNA sequencing, the subject-matter is subjected to an assessment of inventive step.

D3 is considered to be the closest prior art. Therein the authors provide several human proteins having transmembrane domains and DNAs encoding these proteins. The objective problem is defined as the provision of further human proteins bearing hydrophobic domains.

It is common knowledge to the skilled person that the predicted protein sequence of cloned cDNA sequences give a strong indication as to whether a protein is secreted

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and or possesses a transmembrane domain. Indeed D3 teaches just that. Consequently, no inventive step may be recognise for such subject-matter. Moreover, the provision of antibodies directed against said protein sequences do not require inventive activity. Thus claims 1 to 7 do not meet with the requirements of Article 33 (3) PCT.

Furthermore the provision of naturally occurring sequences possessing hydrophobic domains are not susceptible to industrial application. Thus, claims 1 to 7 do not conform with Article 33 (4) PCT.